

In the Claims:

Please amend Claims 3, 5, 7, 8, 10-24, 27, 28, 30, 32-37, 39, 41-47, and 50 as shown below and cancel Claims 25, 26, 48, and 49 without prejudice prior to calculating the fees due for this patent application. A complete copy of the claims including marked-up versions of each claim which is amended in this Preliminary Amendment appears below.

1     1.     (Original) A heart valve prosthesis having a plurality of leaflets encircling a flow  
2     opening and of size to coapt to form a valve, each leaflet having a free outflow edge at  
3     the outflow end of the leaflet, wherein the free outflow edge forms a convex (relative to  
4     the leaflet) curve in the plane of the leaflet.

1     2.     (Original) A method for forming a heart valve prosthesis comprising the step of  
2     forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to  
3     form a valve, wherein each leaflet has a free outflow edge at the outflow end of the  
4     leaflet, wherein the free outflow edge forms a convex (relative to the leaflet) curve in the  
5     plane of the leaflet.

1     3.     (Currently Amended) A method for forming a heart valve prosthesis comprising  
2     the steps of:

assembling the valve, by steps comprising forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a valve, and forming an outer sheet joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets ~~join~~, join;

after assembly of at least the leaflets and outer sheet of the valve, shaping the leaflets and/or outer sheet to a desired ~~shape~~, shape; and

fixing the leaflets and/or outer sheet of the valve in the desired shape.

4. (Original) The method of claim 3 wherein the leaflets and outer sheet are shaped to a desired shape and fixed in the desired shape, and wherein the shaping of the outer sheet is of a portion of the outer sheet on the outflow side of the join between the outer sheet and the leaflets around the inflow end.

5. (Currently Amended) A method for forming a stentless heart valve prosthesis comprising the steps of:

forming a plurality of leaflets joined to encircle a flow passage and of a size to coapt to form a ~~valve~~, valve; and

forming an outer sheet joined to the leaflets around an inflow end and along commissures formed where adjacent leaflets ~~join~~, join;

wherein the join between the outer sheet and the leaflets around the inflow end is at the periphery of the leaflets, and the outer sheet extends by a distance between 0.3 and 4mm

9 beyond the join with the leaflets at the inflow end, on the inflow side of the join, or the  
10 join between the outer sheet and the leaflets around the inflow end is at the periphery of  
11 the outer sheet, and the leaflets extend by a distance between 0.3 and 4mm beyond the  
12 join with the outer sheet at the inflow end, on the inflow side of the join.

1 6. (Original) The method of claim 5, further comprising the step of after assembly of  
2 at least the leaflets and outer sheet of the valve, shaping the leaflets and/or outer sheet to  
3 a desired shape and fixing the leaflets and/or outer sheet of the valve in the desired shape.

1 7. (Currently Amended) The method of ~~any one of claims 5, 3 to 6~~ wherein each  
2 leaflet has a free outflow edge at the outflow end of the leaflet, wherein the free outflow  
3 edge forms a convex (relative to the leaflet) curve in the plane of the leaflet.

1 8. (Currently Amended) The method of ~~any one of claims 3, 4, 6 or 7~~ wherein the  
2 leaflets and/or outer sheet are shaped to a desired shape by inserting a shaping device into  
3 a pocket formed by a leaflet and the outer sheet.

1 9. (Original) The method of claim 8 wherein the shaping device is a ball formed of a  
2 resilient material, preferably cotton wool.

1 10. (Currently Amended) The method of ~~any one of claims 3, 4, 6 to 9~~ wherein the  
2 leaflets and outer sheet are assembled from pericardium which has not been fixed, and  
3 fixing the leaflets and/or outer sheet of the valve in the desired shape is performed by  
4 treatment with glutaraldehyde.

1 11. (Currently Amended) The method of ~~any one of claims 3, 4, 6 to 10~~ wherein after  
2 assembly and fixing of the valve the outer sheet is trimmed close to the join between the  
3 outer sheet and the leaflets on the outflow side of the join.

1 12. (Currently Amended) A valve obtainable by the method of ~~any one of claims 5, 2,~~  
2 ~~4 to 11.~~

1 13. (Currently Amended) A stentless heart valve prosthesis comprising a plurality of  
2 leaflets joined to encircle a flow passage and of a size to coapt to form a valve, an outer  
3 sheet joined to the leaflets around an inflow end and along commissures formed where  
4 adjacent leaflets join, wherein the join between the outer sheet and the leaflets around the  
5 inflow end is at the periphery of the leaflets, and the outer sheet extends by a distance  
6 between 0.3 and 4mm beyond the join with the leaflets at the inflow end, on the inflow  
7 side of the join, or the join between the outer sheet and the leaflets around the inflow end  
8 is at the periphery of the outer sheet, and the leaflets extend by a distance between 0.3

9 and 4mm beyond the join with the outer sheet at the inflow end, on the inflow side of the  
10 join.

1 14. (Currently Amended) The heart valve prosthesis of claim 13 wherein the outer  
2 sheet of the valve has a shape resembling the shape of natural aortic sinuses.

1 15. (Currently Amended) The heart valve prosthesis of claims 13 ~~or 14~~ wherein the  
2 outer sheet is trimmed close to the join between the outer sheet and the leaflets on the  
3 outflow side of the join.

1 16. (Currently Amended) The heart valve prosthesis of claim 13, ~~14 or 15~~ wherein  
2 each leaflet has a free outflow edge at the outflow end of the leaflet, wherein the free  
3 outflow edge forms a convex (relative to the leaflet) curve in the plane of the leaflet.

1 17. (Currently Amended) The heart valve prosthesis ~~or method of any of the preceding~~  
2 claims 13 wherein the valve has three leaflets.

1 18. (Currently Amended) The heart valve prosthesis ~~or method of any of the preceding~~  
2 claims 13 wherein the valve is stentless.

1 19. (Currently Amended) The heart valve prosthesis ~~or method~~ of claim 1 ~~or 2~~  
2 wherein the valve comprises an outer sheet joined to the leaflets around an inflow end  
3 and along commissures formed where adjacent leaflets join.

1 20. (Currently Amended) The heart valve prosthesis ~~or method of any one of the~~  
2 ~~preceding~~ claims 13 wherein the leaflets and/or outer sheet (where present) are formed  
3 from material other than natural valve material.

1 21. (Currently Amended) The heart valve prosthesis ~~or method~~ of claim 20 wherein  
2 the leaflets are formed from a sheet material.

1 22. (Currently Amended) The heart valve prosthesis ~~or method of claim 20 or 21~~  
2 wherein the leaflets and/or outer sheet are formed from a biological material.

1 23. (Currently Amended) The heart valve prosthesis ~~or method of any one of the~~  
2 ~~preceding~~ claims 22 wherein the leaflets and/or outer sheet are formed from pericardium.

1 24. (Currently Amended) The heart valve prosthesis ~~or method of any one of the~~  
2 ~~preceding~~ claims 13 wherein the leaflets are formed by a single piece of sheet material.

1 25. (Cancelled) A valve prosthesis ~~according to any one of the preceding claims for~~  
2 ~~use in medicine.~~

1 26. ~~(Cancelled) Use of a valve prosthesis according to any one of the preceding claims~~  
2 ~~in the manufacture of a medicament for the treatment of a patient in need of repair or~~  
3 ~~replacement of a heart valve.~~

1 27. (Currently Amended) A method of repairing a heart valve comprising the step of  
2 providing a heart valve prosthesis as defined in ~~any one of the preceding claims~~ 13, and  
3 suturing the heart valve prosthesis to the heart or blood vessel tissue of the patient.

1 28. (Currently Amended) A method of repairing a heart valve comprising the steps of:  
2 (1) providing a valve prosthesis as defined in any one of the preceding claims,  
3 wherein the valve has an outer sheet;  
4 (2) if not already done, trimming the outer sheet close to the join between the outer  
5 sheet and the leaflets on the outflow side of the join; and  
6 (3) suturing the valve prosthesis to the heart or blood vessel tissue of the patient  
7 with a single suture row.

1 29. (Original) A stentless heart valve prosthesis suitable for replacement of the aortic  
2 root comprising an outer wall and a plurality of leaflets positioned inside the outer wall,  
3 encircling a flow opening and of size to coapt to form a valve, wherein the outer wall and  
4 leaflets are formed from material other than natural valve material.

1 30. (Currently Amended) A method for forming a stentless heart valve prosthesis  
2 suitable for replacement of the aortic root ~~as defined in claim 29~~ comprising the steps of  
3 forming an outer wall and a plurality of leaflets positioned inside the outer wall,  
4 encircling a flow opening and of size to coapt to form a valve, wherein the outer wall and  
5 leaflets are formed from material other than natural valve material.

1 31. (Original) A stentless heart valve prosthesis suitable for replacement of the aortic  
2 root comprising a plurality of leaflets joined to encircle a flow passage and of a size to  
3 coapt to form a valve, an outer wall joined to the leaflets around an inflow end and along  
4 commissures formed where adjacent leaflets join, wherein the outer wall and leaflets are  
5 formed from material other than natural valve material, wherein the join between the  
6 outer wall and the leaflets around the inflow end is at the periphery of the leaflets, and the  
7 outer wall extends by a distance between 0.3 and 4mm beyond the join with the leaflets at  
8 the inflow end, on the inflow side of the join, or the join between the outer sheet and the  
9 leaflets around the inflow end is at the periphery of the outer sheet, and the leaflets  
10 extend by a distance between 0.3 and 4mm beyond the join with the outer wall at the  
11 inflow end, on the inflow side of the join.

1 32. (Currently Amended) The heart valve prosthesis of claim 29 ~~or 31 or method of~~  
2 ~~claim 30~~ wherein the outer wall is formed from a biological material (other than natural  
3 valve material) and a non-biological, biocompatible material.



1 33. (Currently Amended) The heart valve prosthesis ~~or method~~ of claim 32 wherein  
2 the outer wall is formed from pericardium and a woven fabric, preferably polyester  
3 (PET).

1 34. (Currently Amended) The heart valve prosthesis ~~or method~~ of ~~any one of~~ claims  
2 31 ~~29 to 33~~ wherein the leaflets are formed from a biological material, for example  
3 pericardium.

1 35. (Currently Amended) The heart valve prosthesis ~~or method~~ of ~~any one of~~ claims  
2 31 ~~29 to 34~~ wherein each leaflet has a free outflow edge at the outflow end of the leaflet,  
3 wherein the free outflow edge forms a convex (relative to the leaflet) curve in the plane  
4 of the leaflet.

1 36. (Currently Amended) The method of ~~any one of~~ claims 30 ~~to 35~~ comprising the  
2 steps of:

3 assembling the valve, by steps comprising forming a plurality of leaflets joined to  
4 encircle a flow passage and of a size to coapt to form a valve, and forming an outer wall  
5 joined to the leaflets around an inflow end and along commissures formed where adjacent  
6 leaflets join;

7 after assembly of at least the leaflets and outer wall of the valve, shaping the  
8 leaflets and/or outer wall to a desired ~~shape~~, shape, and

9           fixing the leaflets and/or outer wall of the valve in the desired shape.

1    37.   (Currently Amended) The method of ~~any one of~~ claims 30 to 35 comprising the  
2    steps of:

3           forming a plurality of leaflets joined to encircle a flow passage and of a size to  
4    coapt to form a valve; and

5           forming an outer wall joined to the leaflets around an inflow end and along  
6    commissures formed where adjacent leaflets join;

7    wherein the join between the outer wall and the leaflets around the inflow end is at the  
8    periphery of the leaflets, and the outer wall extends by a distance between 0.3 and 4mm  
9    beyond the join with the leaflets at the inflow end, on the inflow side of the join; or the  
10   join between the outer wall and the leaflets around the inflow end is at the periphery of  
11   the outer wall, and the leaflet extends by a distance between 0.3 and 4mm beyond the join  
12   with the outer wall at the inflow end, on the inflow side of the join.

1    38.   (Original) The method of claim 37 further comprising the steps of after assembly  
2    of at least the leaflets and outer wall of the valve, shaping the leaflets and/or outer wall to  
3    a desired shape and fixing the leaflets and/or outer wall of the valve in the desired shape.

1 39. (Currently Amended) The method of claim ~~36 or~~ 38 wherein the leaflets and/or  
2 outer sheet are shaped by inserting a shaping device into a pocket formed by a leaflet and  
3 the outer wall.

1 40. (Original) The method of claim 39 wherein the shaping device is a ball formed of  
2 a resilient material, for example cotton wool.

1 41. (Currently Amended) The method of ~~any one of claims 36, 38 to 40~~ wherein the  
2 outer wall is shaped to a desired shape and fixed in the desired shape.

1 42. (Currently Amended) The method of ~~any one of claims 36, 38 to 41~~ wherein the  
2 leaflets and outer sheet are assembled from pericardium which has not been fully fixed,  
3 and fixing the leaflets and/or outer sheet of the valve in the desired shape is performed by  
4 treatment with glutaraldehyde.

1 43. (Currently Amended) The method ~~or valve prosthesis of any one of claims 37 29~~  
2 ~~to 42~~ wherein the outer wall or sheet has a height (ho) that is between 1 and 15 cm,  
3 preferably between 4 and 12 cm, still more preferably between about 8 and 10 cm greater  
4 than the maximum height (h) of the leaflets.

1 44. (Currently Amended) A stentless heart valve prosthesis suitable for replacement of  
2 the aortic root obtained or obtainable by a method according to ~~any one of claims 37, 30,~~  
3 ~~32 to 42.~~

1 45. (Currently Amended) The heart valve prosthesis of ~~any one of claims 29, 31 to 35,~~  
2 ~~43 or 44~~ wherein the outer sheet of the valve has a shape resembling the shape of natural  
3 aortic sinuses.

1 46. (Currently Amended) The heart valve prosthesis ~~or method of any one of claims~~  
2 ~~44 29 to 45~~ wherein the valve has three leaflets.

1 47. (Currently Amended) The heart valve prosthesis ~~or method of any one of claims~~  
2 ~~44 29 to 46~~ wherein the leaflets are formed by a single piece of sheet material.

1 48. (Cancelled) ~~A valve prosthesis according to any one of claims 29 to 47 for use in~~  
2 ~~medicine.~~

1 49. (Cancelled) ~~The use of a valve prosthesis according to any one of claims 29 to 48~~  
2 ~~in the manufacture of a medicament for the treatment of a patient in need of repair or~~  
3 ~~replacement of a heart valve and in need of replacement of a portion of the aortic wall.~~

1 50. (Currently Amended) A method for repairing a heart valve comprising the step of  
2 providing a valve prosthesis according to ~~any one of claims 44, 29 to 49,~~ and suturing the  
3 valve prosthesis to the heart or blood vessel tissue of the patient.

1 51. (Original) The method of claim 50 comprising the step of trimming the outer wall  
2 to the desired length, depending on the extent of aortic tissue to be replaced.